

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
SOUTHERN DIVISION**

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
 v.) Civil No. 05-3494-CV-S-FJG
)
VITA-ERB, LTD., a business;)
and MARY BARNES,)
MOSES R. BARNES, and)
FRED R. PAULICKA, PH.D.,)
individuals,)
)
Defendants.)

ORDER

Pending before the Court is Plaintiff's Motion for Summary Judgment (Doc. No. 29).

Also before the Court are Plaintiff's Suggestions in Support of its Motion for Summary Judgment (Doc. No. 30), Defendants' Suggestions in Opposition to Plaintiff's Motion for Summary Judgment and Consent to Entry of Order of Injunction by Defendants Mary Barnes and Moses R. Barnes (Doc. No. 39), and Plaintiff's Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment (Doc. No. 42).

I. Facts

Defendant Vita-Erb, Ltd. ("Vita-Erb") is a privately-owned business incorporated in the State of Illinois in 1978, and doing business at 1358 N. Stewart Street, Springfield, Missouri 65802.¹ Defendant Mary Barnes is the President and co-owner of Vita-Erb. She

¹Notably, as discussed in Plaintiff's reply, defendants have failed to properly controvert the material facts detailed in plaintiff's motion. In accordance with Local Rule 56.1(a), "[a]ll facts set forth in the statement of the movant shall be deemed admitted for the purpose of summary judgment unless specifically controverted by the opposing party." See Ruby v. Springfield R-12 Public School Dist., 76 F.3d 909, 911 n. 6 (8th Cir. 1996). On a related note, defendants in their response indicate, without

is present at the firm on a daily basis and has authority over the administrative duties, financial operations, and acquisition of new customers for the firm. Defendant Moses R. Barnes is the husband of Mary Barnes and is the Vice- President and co-owner of Vita-Erb. He is present at the firm on a daily basis and is the firm's Quality Assurance Director. Mr. Barnes is responsible for overseeing the receipt of raw materials and the manufacture, packaging, and distribution of products. Defendant Fred R. Paulicka, Ph.D., resides outside the State of Missouri, but has visited Missouri on various occasions. Dr. Paulicka is Vita-Erb's consultant, and he helped create the labeling for "The Original Cell Revitalizer." Dr. Paulicka is the author of a letter dated October 5, 1999 ("the Paulicka Letter") that accompanies shipments of "The Original Cell Revitalizer" in interstate commerce. At Dr. Paulicka's request, Mr. Barnes includes copies of the Paulicka Letter in shipments of "The Original Cell Revitalizer" and "Cell Revitalizer." Dr. Paulicka also participated in a compliance meeting with the U.S. Food and Drug Administration ("FDA") regarding Vita-Erb's manufacturing deficiencies.

Defendants are engaged in the business of manufacturing drugs that include, but are not limited to, medicated shampoos, pain relieving gels, and antimicrobial hand cleansers. Defendants also manufacture a liquid herbal-extract drug product. Products manufactured by Vita-Erb include: (a) "Super Duper Diaper Doo"; (b) "Obedience Medicated Shampoo C-S-S"; (c) "Obedience Medicated Shampoo S-S"; (d) "Handcleaner,

providing evidentiary support for their assertions, that (1) defendant Vita-Erb Ltd. is no longer an active entity in that it has been involuntarily dissolved and therefore it should be dismissed from this action; (2) defendant Paulicka should be dismissed from this action because he has no ownership interest in defendant Vita-Erb, Ltd.; and (3) defendants are no longer producing the "drugs" referenced in plaintiff's complaint.

Waterless Cream Form - Antimicrobial"; (e) "Vita Erb Arthritis Pain Relief"; (f) "PES 828 Pain Relieving Gel With Ilex"; (g) "Medi-Derm Analgesic Lotion"; (h) "Doctor's Best Super Diaper Ointment"; (i) "SewSoft Pain Relieving Gel"; (j) "PES Clean Instant Antiseptic Handcleaner"; (k) "Medicated Shampoo Coal Tar 1%"; (l) "Pain Freeze Pain Relieving Gel"; and (m) "Valley-Of-Youth R-Thritis Relief Roll-On." Vita-Erb also manufactures and distributes a liquid herbal-extract product labeled and/or promoted under various names, including "The Original Herbal Tea Concentrate," "The Original Cell Revitalizer," and "Cell Revitalizer." Vita-Erb manufactures products (a) through (m), above, using one or more components that it has received in interstate commerce. Vita-Erb distributes or has distributed the products listed above (except Medicated Shampoo Coal Tar 1%) in interstate commerce, or has caused them to be introduced or delivered for introduction into interstate commerce.

FDA has conducted eight inspections of Vita-Erb since 1997. During the most recent inspection of Vita-Erb, conducted between October 18-20, 2005, FDA found significant deviations from FDA's current good manufacturing practice ("CGMP") regulations for finished pharmaceuticals. See 21 C.F.R. pts. 210 and 211. FDA conducted previous inspections of Vita-Erb between March 3-10, 2005; August 23-30, 2004; October 27 and November 12, 2003; February 19 and March 4, 2003; April 29 and May 2, 2002; September 29 and October 1, 1999; and December 11-12, 1997. During each of these inspections, FDA documented many of the same or similar CGMP violations that were observed during the most recent inspection. At the conclusion of each of inspection, FDA issued a List of Inspectional Observations Form FDA-483 ("Form FDA-483") to Vita-Erb identifying the violations of CGMP observed during the underlying inspection. FDA also issued two

Warning Letters to Defendants, one following the December 1997 inspection and the other following the April/May 2002 inspection, that warned Defendants of their significant deviations from CGMP.

Defendants responded to the Form FDA-483s and both Warning Letters with promises of corrective action. Additionally, in August 2002, a compliance meeting was held at FDA's Kansas City District Office so that FDA officials could discuss the firm's CGMP deficiencies with Dr. Paulicka and Mr. Barnes. During this compliance meeting, Dr. Paulicka and Mr. Barnes again promised corrective action. Subsequent inspections, however, revealed continuing CGMP deviations. Mary and Moses Barnes admit that "certain processes employed by Defendant Vita-Erb may not totally conform to FDA's CGMP regulations."

In addition to the two previously-mentioned Warning Letters issued to Defendants regarding their violations of the CGMP regulations, FDA issued a third Warning Letter to Defendants on April 29, 2004, because defendants manufacture and distribute unapproved new drugs and misbranded drugs. Followup inspections and investigations conducted by FDA since the April 29, 2004 Warning Letter reveal that Defendants commenced manufacturing "SewSoft Pain Relieving Gel" and that Defendants have changed the name of their liquid herbal-extract drug product from "The Original Cell Revitalizer" and "Cell Revitalizer" to "The Original Herbal Tea Concentrate."

In late-March 2005, an FDA investigator made an undercover purchase of Vita- Erb's liquid herbal-extract product, "The Original Herbal Tea Concentrate," from Defendants. On March 25, 2005, a package arrived at the address provided by the undercover FDA investigator. The package contained the following address for the vendor, Vita-Erb: "1358

N. Stewart, Springfield, MO 65802." This package included the following contents: three bottles of "The Original Herbal Tea Concentrate," a letter from a "Dr. Ronald Phelps," an ingredient list entitled "Ingredients of the Herb Tea as of September 15, 1978," and an invoice for the product. The letter from Dr. Ronald Phelps contains the following statements regarding the liquid herbal-extract product: "I have observed a reduction in prostate P.S.A. [Prostate-Specific Antigens] after certain patients with high levels have taken [Cell Revitalizer] after a short period of time."

In September 2005, an FDA investigator completed another undercover purchase of "The Original Herbal Tea Concentrate" in interstate commerce. On September 13, 2005, a package from Vita-Erb was delivered by Federal Express to the Kansas address that the undercover FDA investigator had provided to Mr. Barnes. This package also contained the following address of the vendor, Vita-Erb: "1358 N. Stewart, Springfield, MO 65802." The package contained three 16 ounce bottles of "The Original Herbal Tea Concentrate." On or around September 23, 2005, an envelope from Vita-Erb also arrived at this address. This envelope also contained the following return address: "Vita-Erb, Ltd., 1358 N. Stewart, Springfield, MO 65802." This envelope contained a letter entitled "Components Of The Herb Tea As Of September 15, 1978." On September 21, 2005, an envelope addressed to "Francis Fox" arrived at 410 N. Persimmon Drive, Olathe, Kansas 66061. The envelope contained an original invoice from Vita-Erb for the herbal tea product and a copy of the invoice.

II. Standard

Summary judgment is appropriate if the movant demonstrates that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of

law. Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). The facts and inferences are viewed in the light most favorable to the nonmoving party. Fed. R. Civ. P. 56(c); Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-590 (1986). The moving party must carry the burden of establishing both the absence of a genuine issue of material fact and that such party is entitled to judgment as a matter of law. Matsushita, 475 U.S. at 586-90.

Once the moving party has met this burden, the nonmoving party may not rest on the allegations in the pleadings, but by affidavit or other evidence, must set forth facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e); Lower Brule Sioux Tribe v. South Dakota, 104 F.3d 1017, 1021 (8th Cir. 1997). To determine whether the disputed facts are material, courts analyze the evidence in the context of the legal issues involved. Lower Brule, 104 F.3d at 1021. Thus, the mere existence of factual disputes between the parties is insufficient to avoid summary judgment. Id. Rather, "the disputes must be outcome determinative under prevailing law." Id. (citations omitted).

III. Discussion

Plaintiff has moved for summary judgment on the above facts, and seeks a permanent injunction pursuant to 21 U.S.C. § 332(a), enjoining defendants from manufacturing and distributing drugs. Plaintiff has provided a proposed permanent injunction for the Court's review. Defendants argue in response that defendants Paulicka and Vita-Erb, Ltd. should be dismissed from this case, as Paulicka is not an owner of the company, and Vita-Erb, Ltd. is no longer a legal entity. Defendants Mary Barnes and Moses R. Barnes indicate that they have no objection to being enjoined from the future manufacture and production of the drugs described in plaintiff's complaint, and provide their

own proposed Order of Injunction that they believe would resolve plaintiff's concerns. In its reply, plaintiff indicates the proposed Order of Injunction provided by defendants would be inadequate, in that, among other things, (1) it does not enjoin defendant Paulicka, who (even if he is not a co-owner) is responsible for his actions as Vita-Erb's consultant and actively participated in the violations of the FDCA by causing the distribution of unapproved new drugs into interstate commerce; (2) it does not enjoin defendant Vita-Erb, Ltd., because even if Vita-Erb, Ltd. has been involuntarily dissolved, an injunction may be used against a dissolved corporation to bind a resurrected or successor corporation (see Golden State Bottling Co. v. NLRB, 414 U.S. 168 (1973)); (3) it only enjoins the manufacture of drugs at Vita-Erb's current facility, which would allow the defendants to evade the Court's Order by merely changing their business location; and (4) it omits provisions allowing the FDA to undertake swift action to shut down defendants' operations upon a finding of violations of the Court's injunction order without further order of the Court.

Having considered the record in this matter, the Court finds that Plaintiff's Motion for Summary Judgment (Doc. No. 29) establishes that there is no genuine issue as to any material fact in this proceeding and that Plaintiff is entitled to judgment as a matter of law on its Amended Complaint For Permanent Injunction (Doc. No. 21). Defendants Vita-Erb, Ltd. (hereafter, "Vita-Erb"), Mary Barnes, Moses R. Barnes, and Fred R. Paulicka, Ph.D., (collectively, "Defendants"), have violated and are now violating the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act") by introducing adulterated, misbranded, and unapproved new drugs into interstate commerce and by holding adulterated and misbranded drugs for sale after one or more components of such drugs are shipped in interstate commerce. The Court further finds that the proposed Order of

Permanent Injunction supplied by plaintiff ought to be entered in this matter, as defendants' proposal does not sufficiently protect the interests of the plaintiff or consumers.

Accordingly, the Court enters the following **PERMANENT INJUNCTION**:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action, and the Complaint and Amended Complaint state a cause of action under the Act 21 U.S.C. §§ 301-397.

2. Defendants have violated and now violate the Act, 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(l).

3. Defendants have violated and now violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

4. Defendants have violated and now violate the Act, 21 U.S.C. § 331(k), by causing drugs within the meaning of 21 U.S.C. § 321(g)(1) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

5. Defendants have violated and now violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are misbranded within the meaning of 21 U.S.C. § 352(a) and (e)(1)(A)(ii).

6. Defendants have violated and now violate the Act, 21 U.S.C. § 331(k), by causing drugs within the meaning of 21 U.S.C. § 321(g)(1) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(a) and (e)(1)(A)(ii).

7. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent equity power of this Court, from directly or indirectly doing or causing the manufacture, processing, packing, labeling, holding, and distribution of all drugs within the meaning of 21 U.S.C. § 321(g)(1) unless and until:

Current Good Manufacturing Practice

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with current good manufacturing practice ("CGMP"). See 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "expert"), to make inspections of their drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement with Defendants) to Defendants or their immediate families.

Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity of the expert as soon as they retain such expert;

C. The expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs, and the expert determines whether Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs are in compliance with CGMP;

D. The expert certifies in writing to FDA that: (1) he or she has inspected Defendants' facilities, processes, and controls; (2) all CGMP deviations brought to Defendants' attention by FDA or otherwise have been corrected; and (3) such facilities, processes, and controls are in compliance with CGMP. As part of this certification, the expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations brought to Defendants' attention by FDA or by any other person; and (2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are and continuously will be operated and administered in conformity with CGMP;

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Order have been met, and whether Defendants' facilities are otherwise operated in conformity with paragraphs 7(A)-(E), the Act, and its implementing regulations;

Unapproved New Drugs

G. For any drug identified in Appendix A, any product containing the same or similar ingredients as those identified in Appendix A, any product labeled as being similar in composition or effect to the drugs identified in Appendix A, or any other drug within the meaning of 21 U.S.C. § 321(g):

1. an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;
2. an investigational new drug application filed pursuant to 21 U.S.C. § 355(l) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or
3. such drug product conforms strictly to all of the requirements set forth in any of the United States Food and Drug Administration ("FDA") monographs, 21 C.F.R. § Part 330;

H. For any drug identified in Appendix A, any product containing the same or similar ingredients as those identified in Appendix A, or any product labeled as being similar in composition or effect to any drug identified in Appendix A that Defendants plan to manufacture or distribute upon receiving written notification pursuant to paragraph 7(J), Defendants submit to FDA the drug's proposed labeling, and any other information required by FDA, for review and shall demonstrate to FDA, as FDA deems appropriate, that the drug product strictly conforms to an FDA drug monograph, is the subject of an approved new drug application under 21 U.S.C. § 355(a), or is the subject of an investigational new drug application under 21 U.S.C. § 355(l). FDA will notify Defendants in writing, within sixty (60)

calendar days of receiving the proposed labeling and other information, whether the drug is capable of being manufactured and distributed under the Act;

Misbranding

I. For any drug identified in Appendix B, any product containing the same or similar ingredients as those identified in Appendix B, or any product labeled as being similar in composition or effect to the drugs identified in Appendix B that Defendants plan to manufacture or distribute upon receiving written notification pursuant to paragraph 7(J), Defendants submit to FDA the drug's proposed labeling, and any other information required by FDA, for review and shall demonstrate to FDA, as FDA deems appropriate, that the drug's labeling strictly conforms to the Act. FDA will notify Defendants in writing, within sixty (60) calendar days of receiving the proposed labeling and other information, whether the drug is capable of being manufactured and distributed under the Act; and

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 7(A)-(I).

8. Upon entry of this Order, Defendants and each an all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equity power of this Court from directly or indirectly doing of causing to be done any act that:

A. Violates 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21

U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(l);

B. Violates 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violates 21 U.S.C. § 331(k), by causing drugs within the meaning of 21 U.S.C. § 321(g)(1) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

D. Violates 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are misbranded within the meaning of 21 U.S.C. § 352; and

E. Violates 21 U.S.C. § 331(k), by causing drugs 21 U.S.C. § 321(g)(1) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352.

9. After Defendants have complied with paragraphs 7(A)-(I) and receive written notice from FDA pursuant to paragraph 7(J), Defendants shall retain an independent person or persons (the "auditor"), without personal, financial (other than the consulting agreement with Defendants), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to assess Defendants' compliance with CGMP, and to conduct audit inspections of their drug manufacturing operations. The auditor shall conduct these inspections at least once every six (6) months

for a period of five (5) years. If Defendants choose, the auditor may be the same person or persons retained pursuant to paragraph 7(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report analyzing whether Defendants are in compliance with CGMP and identifying all deviations from CGMP and the Act. Beginning with the second audit report, the auditor shall assess the adequacy of any actions taken by Defendants to correct all previously observed CGMP deviations, and include this information in the audit report. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the inspections are completed. In addition, Defendants shall maintain the audit reports in a separate file at their facility and shall make the audit reports available to FDA upon request.

B. If an audit report contains any CGMP deviations or other violations of the Act, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those deviations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, propose a schedule for completing corrections. The proposed schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, or within the time period otherwise approved by FDA, the auditor shall review the actions taken by Defendants to correct the CGMP deviations. Within five (5) business days of beginning that

review, the auditor shall report in writing to FDA whether each of the CGMP deviations has been corrected and, if not, which violations were not corrected.

10. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, the analyses of a sample or samples, a report or data prepared or submitted by Defendants, the expert, the auditor, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, the CGMP regulations, or this Order, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, including, but not limited to, one or more of the following:

- A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);
- B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Order;
- C. Submit additional reports or information to FDA;
- D. Recall specified drugs manufactured and/or distributed by Defendants. Defendants shall bear the costs of such recall(s); or
- E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants into compliance with the Act, the CGMP regulations, or this Order.

11. Upon receiving an order from FDA as described in paragraph 10, Defendants shall immediately comply with FDA's order and continue to comply with FDA's order until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act, the CGMP regulations, and the requirements of this Order, and that Defendants may, therefore, resume operations.

12. Within fifteen (15) business days from the date of entry of this Order, Defendants shall destroy, under FDA supervision: (a) all of Vita-Erb's drugs identified in Appendix A and B, any product containing the same or similar ingredients as those identified in Appendix A and B, and any product labeled as being similar in composition or effect to the drugs identified in Appendix A and B in Defendants' possession, custody, and/or control; and (b) all other Vita-Erb drug products that were manufactured before the date on which this Order was entered and, therefore, are adulterated because they were not manufactured, processed, packaged, labeled, held, and distributed in accordance with CGMP. Defendants shall not dispose of any drug products in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969. All costs of destruction shall be borne by Defendants. The costs of FDA's supervision of the destruction shall be borne by Defendants, at the rates specified in paragraph 14.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all drugs, including components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The

inspection authority granted by this Order is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Order or that FDA deems necessary to evaluate Defendants' compliance with this Order. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed by the parties, these rates are: \$76.10 per hour and fraction thereof per representative for inspection work; \$91.18 per hour or fraction thereof per representative for analytical or review work; \$0.485 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, and post a copy of this Order in the employee common areas at their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Order, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the

provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Order.

16. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor business, the creation of subsidiaries, or any other change in the business structure of Vita-Erb or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assign at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

17. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Order shall be addressed to the Director, FDA Kansas City District Office, 11630 West 80th Street, Lenexa, Kansas 66214.

18. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Order, Defendants agree to pay attorney fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

19. Defendants shall abide by all decisions of FDA, which decisions shall be final. FDA decisions under this Order shall be reviewed by the Court, if contested by Defendants, under the arbitrary and capricious standard, 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be conducted

without any discovery by either party and shall be based exclusively on the written record before FDA at the time the decision was made.

20. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED.

Date: November 14, 2006
Kansas City, Missouri

S/ FERNANDO J. GAITAN, JR.
Fernando J. Gaitan, Jr.
United States District Judge

APPENDIX A: The Adulterated and Unapproved New Drugs

1. THE ORIGINAL HERBAL TEA CONCENTRATE
2. THE ORIGINAL CELL REVITALIZER
3. CELL REVITALIZER
4. SEWSOFT PAIN RELIEVING GEL
5. PES INSTANT ANTISEPTIC HANDCLEANER
6. OBEDIENCE MEDICATED SHAMPOO S-S

APPENDIX B: The Adulterated and Misbranded Drugs

1. PES 828 PAIN RELIEVING GEL WITH ILEX
2. MEDI-DERM ANALGESIC LOTION